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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
03/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/675,509	FULTON ET AL.	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/10/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10 and 33-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *10, 33, 36-39* is/are allowed.

6)☒ Claim(s) *34,35 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Amendment and Response, filed 12/10/07, has been entered. Claims 36-39 are amended; claim 40 is added; claims 10 and 33-40 are pending and under current examination.

Claim Rejections - 35 USC § 112 - Enablement

The prior rejection of claims 36-39 under 35 U.S.C. 112, first paragraphis withdrawn in view of Applicants' amendment to the claims, which now recite that the bacterium are isolated.

Written Description

Claims 34-35 and newly added claim 40 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants Arguments. Applicants argue that the claims are described, because the Examiner's assertions suggesting that a 200 nucleotide segment 18.7% of the total length of SEQ ID NO: 1 is irrelevant to determine as to whether there is adequate written description for the instant claims. Applicants argue that in this regard, each and every nucleotide of SEQ ID NO: 3 is provided in the application, therefore, each nucleotide of every 200 nucleotide sequence of SEQ ID NO: 3 is inherently described in the Application. Therefore, Applicants argue, that the determination of sequences that are 90% identical to such sequences is trivial to one of ordinary skill in the art.

Additionally, Applicants argue that the instant case is clearly distinguishable from Lilly which provided no description of any sequence to the claimed human

insulin cDNA because each and every nucleotide of SEQ ID NO: 3 is described in the specification. See pages 6-7 of the Response.

Response to Arguments. These arguments are not persuasive. Although each nucleotide sequence of SEQ ID NO: 3 may be disclosed in the specification, there is no description for nucleic acid sequences that are at least 90% identical to 200 nucleotides of SEQ ID NO: 3. Although the disclosure of a single disclosed species may provide an adequate written description for the genus, this is only the case when the species disclosed is representative of the genus. In the instant case, the genus encompasses sequences that have 90% homology to 200 nucleotides of SEQ ID NO: 3. These nucleic acids may encompass polymorphisms, allelic variants, etc. The specification does not provide any guidance for any of the fragments that are encompassed by the claims, other than the full length SEQ ID NO: 3. For example, there is no description of various mutational sites in an allele that would occur in nature, and the general knowledge in the art concerning alleles does not provide any indication of how the structure is representative of unknown alleles. The nature of alleles is that they are variant structures, and in the present state of the art, the structure of one does not provide structure to the others. The common attributes of the genus claimed are not described, and therefore one of skill would conclude that Applicants were not in possession of the claimed genus because the only description that exists is that of the full length, 100% identical SEQ ID NO:3. Additionally, the Examiner's previous interpretation of claim 34 stands:

1. SEQ ID NO: 3 is 1068 nucleotides in length.
2. 200 nucleotides of the total length is approximately 18.7%
3. 90% identical to an equal length of 200 nucleotides is 180 nucleotides.

Thus, Applicants are claiming a sequence that is at least 180 nucleotides identical to an equal length sequence that is only 18.7% of the total length of SEQ ID NO: 3. As stated previously, the specification provides sufficient written description for SEQ ID NO: 3, which encodes thiaminase I from *N. gruberi*, the

specification fails to describe the nucleic acid sequences that are encompassed in claims 34-35 and 40 to indicate that Applicants had possession of the invention.

In particular, the nucleic acids of claims 34-35 fail, although having a particular nucleic acid structure, fail to be described with a particular function, to describe these nucleic acids. There is no guidance as to what the function of nucleic acid sequences would be.

The question is whether or not Applicants, at the time the application was filed, were in possession a representative number of purified, enriched, or isolated nucleic acid sequences, wherein the nucleic acid sequence is at least 90% identical to at least 200 nucleotides in length of the *N. gruberi* thiaminase sequence, as set forth in SEQ ID NO: 3.

Regents of the University of California v. Eli Lilly, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). In *Lilly*, the claim(s) to rat cDNA was required to encoded insulin. Hence, all of the cDNA were functionally limited to those that encoded a specific protein, insulin. However, in the instant case, claims 34-35 no longer have a required function. Claims 34-35 encompass a genus of nucleic acids, are not limited functionally, or by any common characteristics. In *Lilly*, the court, citing *Fiers v. Revel* (984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), expressed that "[a]n adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish to plan for obtaining the claimed chemical invention."

In this respect, one could to state that a claim drawn to rat cDNA, though embracing a plurality of species, were deemed "described" by their "physical properties," that is, they all were limited those which encoded insulin. In the instant situation, Applicants have not disclosed structures of the nucleic acid sequences as set forth in claims 34-35, nor have Applicants described physical properties to which such species would share. The addition of claim 40 does not

remedy this, because it does not provide any guidance for which physical properties a species of nucleic acid, other than full length SEQ ID NO: 3, would have thiaminase activity.

Accordingly, it is maintained that the claims fail to be described by the as-filed disclosure.

Conclusion

Claims 10, 33, 36-39 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (571)272-0736. The examiner can normally be reached on 9-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thaian N. Ton/
Primary Examiner, Art Unit 1632